K010908 (1 of 4)

AUG 1 2001

Medicon eG
Traditional 510(k) - HCH
MEDICON eG · POSTFACH 4455 · D-78509 TUTTLINGEN

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SURGICAL / DENTAL INSTRUMENTS
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2.

510(k) SUMMMARY
of Safety and Effectiveness
+
SE Comparison Table

Medicon eG
[As required by Section 807.92)]

2.1 **Submitter:** [807.92 (a)(1)]

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2.2 **Date Summary Prepared:** [807.92 (a)(1)]
March 3, 2001

2.3 Device Names: [807.92(a)(2)]

Proprieatary	MEDICON Titanium Yasargil Aneurysm Clips
Common	Yasargil Aneurysm Clips
Classification	Clip, Aneurysm

2.4. Reason for Submission: [807.81(2)]

New Device

2.5 Predicate Device [807.92(a)(3)]

Manufacturer	Aesculap Inc. K983758
Proprietary Name	Yasargil Aneurysm Clip
Catalog #`s	FT XXX T
Manufacturer	Mizuho America Inc. K990202
Proprietary Name	Sugita Aneurysm Clips
Catalog #`s	07 XXX-XX

2.6 Device Describtion [807.92(a)(4)]

The MEDICON Titanium Aneurysm Clips will be available as temporary or permanent devices.

The shapes, sizes, and materials used are **substantially equivalent** to those of SE devices.

2.7 Intended Use: [807.92 (a)(5)]

The intended use of the Medicon Titanium Yasargil Aneurysm Clips is to occlude cerebral aneurysms in either temporary or permanent manner. They are applied by MEDICON Clip Appliers.

The Aneurysm Clips are inteded for use and handling by professional and qualified surgeons.

2.8 Environment of Use

The MEDICON Titanium Yasargil Aneurysm Clips are intended for use in healthcare facilities, including hospitals, medical clinics and surgical centers.

Within these facilities the MEDICON Titanium Yasargil Aneurysm Clips may be located in areas where sterile surgical/dental instruments are used such as operating rooms for surgery.

2.9 Difference in Design and Technological Characteristics when Compared to SE Devices

[807.92(a)(6)]

Material: Like the SE devices, the MEDICON Titanium Yasargil Aneurysm Clips are manufactured from nonmagnetic, high quality Titanium Alloy (TiAl6V4) after DIN ISO 5832-3 and ISO 9713.

Design: The design is very similar. Both MEDICON and SE devices consist of various sizes regarding blade length and fenestration diameter and maximum opening of the jaws.

2.10 Discussion of Safety and Effectiveness: [807.92 (b)]

Clinical results of Aneurysm Clips made out of Titanium (TiAl6V4) and manufactured after ISO 9713 have shown their safety and effectivness.

2.11 Industry Standards: [807.92 (d)]

MEDICON certifies compliance with required ISO/EN/ASTM and other device-related standards that apply to the manufacure, packaging, labeling, sterilization, and reprocessing of subject devices including the validation of these processes.

Substantially Equivalent

2.12 Information Bearing on the Safety and Effectiveness:

[807.92 (b)(3)]

The MEDICON Titanium Yasargil Aneurysm Clips have the same intended use as predicate devices. They are made of identical material. The slight differences in design and size do not adversely affect the safety and effectiveness of this Aneurysm Clips.

The results of design validation and clinical testing raise no new issues of safety and effectiveness.

2.13 Comparison with predicate devices (table)

	Medicon	Aesculap	Mizuho
INTENDED USE			
The intended use of Aneurysm Clips is to occlude cerebral aneurysms in either temporary or permanent manner	YES	YES	YES
METHODS OF STERILIZATION			
Steam Sterilization Processes (DIN 58953-9) : 134° C, 2 bar, induction time at least 5 minutes, or 121° C, 1 bar, induction time at least 15 minutes.	YES	YES	YES
MATERIAL			
TiAL6V4 DIN ISO 5832-3	YES	YES	YES
DESIGN			
Colour, Coding	YES	YES	YES
Atraumatic Jaws	YES	YES	YES
Labeling (Packaging shows indications for clip identification)	YES	YES	Assumed
Manufactured after ISO 9713 (Neurosurgical implants: Self-closing intracranial aneruysm clips)	YES	YES	Assumed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Mr. Joachim Schmid
General Manager
Medicon, E.G.
Gaensaecker 15
D-78532 Tuttlingen,
Germany

Re: K010908
Trade/Device Name: Medicon Titanium Yasargil Aneurysm Clips
Regulation Number: 882.5200
Regulatory Class: II
Product Code: HCH
Dated: June 6, 2001
Received: June 13, 2001

Dear Mr. Schmid:

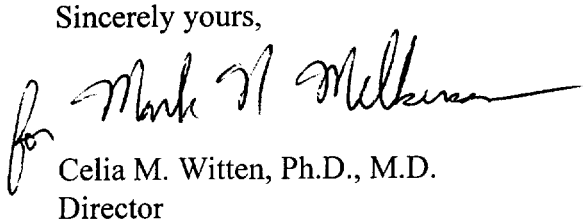
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K010908

Device Name **Medicon Titanium Yasargil Aneurysm Clips**

Classification **Clip, Aneurysm**

Product Code **84 HCH** **Class II** **21 CFR 882.5200**

INDICATIONS FOR USE

The MEDICON Titanium Aneurysmen Clips are to occlude cerebral aneurysms in either a temporary or permanent manner. They are applied by MEDICON Clip Appliers.

The Aneurysm Clips are intended for use and handling by professional and qualified surgeons.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per CFR 801 109) (Optional Format 1-2-96)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010908